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**German diabetes disease management programs are appropriate for  
restructuring care according to the chronic care model: an evaluation with  
the patient assessment of chronic illness care instrument**

Szecsényi, J ; Rosemann, T ; Joos, S ; Peters-Klimm, F ; Miksch, A

**Abstract:** **OBJECTIVE:** With the introduction of diabetes disease management programs (DMPs) in Germany, there is a necessity to evaluate whether patients receive care that is congruent to the Chronic Care Model (CCM) and evidence-based behavioral counseling. We examined differences as perceived and experienced by patients with type 2 diabetes between those enrolled in a DMP compared with patients receiving usual care in two federal states of Germany. **RESEARCH DESIGN AND METHODS:** A random, heterogeneous sample of 3,546 patients (59.3% female) received a mailed questionnaire from their regional health fund, including the German version of the Patient Assessment of Chronic Illness Care (PACIC) instrument, which had additional items for behavioral advice (5A). Two weeks later, a general reminder was sent out. **RESULTS:** A total of 1,532 questionnaires were returned (response rate 42.2%), and valid data could be obtained for 1,399 patients. Mean age of responders was 70.3 years, of which 53.6% were female. Overall, patients enrolled in a DMP scored significantly higher (3.21 of a possible 5) than patients not enrolled in a DMP (2.86) ( $P < 0.001$ ). Significant differences in the same direction were found on all five subscales of the PACIC. For the 5A scales, similar differences were found for all five subscales plus the sum score ( $P < 0.001$ ; mean for DMP = 3.08, mean for non-DMP = 2.78). **CONCLUSIONS:** DMPs, as currently established in primary care in Germany, may impact provided care significantly. The changes in daily practice that have been induced by the DMPs are recognized by patients as care that is more structured and that to a larger extent reflects the core elements of the CCM and evidence-based counseling compared with usual care.

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**German diabetes disease management programs are appropriate to restructure care according to the Chronic Care Model** – An evaluation with the Patient Assessment of Chronic Illness Care (PACIC-5A) instrument.

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## Abstract

**OBJECTIVE:** With the introduction of diabetes disease management programs (DMP) in Germany there is a necessity to evaluate whether patients receive care which is congruent to the chronic care model (CCM) and evidence-based behavioural counselling. We examined differences as perceived and experienced by patients with type 2 diabetes between those enrolled in a DMP compared to patients receiving usual care in two federal states of Germany.

**RESEARCH DESIGN AND METHODS:** A random, heterogeneous sample of 3.546 patients (59.3% female) received a mailed questionnaire from their regional health fund including the German version of the PACIC-5A instrument. Two weeks later a general reminder was sent out.

**RESULTS:** 1.532 questionnaires were returned (response rate 42.2%), valid data could be obtained for 1.399 patients. Mean age of responders was 70.3 years of which 53.6% were female. Overall, patients enrolled in a DMP scored significantly higher (3.21 of a possible 5) than patients not enrolled in a DMP (2.86;  $p < 0.001$ ). Significant differences in the same direction were found on all five subscales of the PACIC. For the 5A scales similar differences were found for all 5 subscales plus the sumscore ( $p < 0.001$ ; mean for DMP=3.08, mean for non-DMP=2.78).

**CONCLUSIONS:** DMPs as currently established in primary care in Germany may impact provided care significantly. The changes in daily practice which have been induced by the DMPs are recognized by patients as care that is more structured and that reflects the core elements of the CCM and evidence-based counselling to a larger extent as usual care.

Abbreviations : CCM, chronic care model; DMP, disease management program ; PACIC-5A, Patient Assessment of Chronic Illness Care including 5A scoring; AOK, regional statutory health fund

Improving the quality of care for patients with type 2 diabetes and other chronic conditions is an important aim of health policy and providers in many countries throughout the world. In countries like the US, disease management programs (DMP) – defined as structured, multifaceted, systematic approaches to provide better care (1) have been introduced by a vast number of ‘players’ and providers with different approaches for more than twenty years (2), showing small to modest results.

In Germany with its statutory health insurance system, insuring approx. 90% of the population, disease management programs were introduced nationwide in 2003 on the basis of a new legislation which aimed to improve the quality of care and to foster competition between health insurances (3,4). In contrast to the US the core content of a DMP in Germany (e.g. evidence-based clinical guidelines, basic data set, quality indicators, transfer between different levels of care, provision of feedback, re-call for patients etc.) is defined by a national expert group and its recommendations are compulsory for contracts between insurers and providers, although there are smaller differences in detail (e.g. type of feedback-report, remuneration etc.) between programs of different contracting partners. Family practitioners (general practitioners, family physicians, and internists in private practice) have a central role in co-ordinating care of enrolled patients.

At the time of their development and introduction the national DMPs were heavily opposed by the medical profession (5, 6) under arguments such as being ‘cookbook medicine’, providing ‘suboptimal care’ or that recommendations which were given are not new but are already fully implemented into routine daily practice (7). The DMP for type-2 diabetes was first introduced in 2003. By the mid of 2007 about 2.3 million patients with type-2 diabetes (approx. 50% of the estimated number of patients in the population) and 30.300 family practices (approx. 65%) are actively enrolled (8). Still a reasonable number of physicians

refuse to take part. Enrolment of a patient for the programme requires prior enrolment of the family physicians of the practice. If the doctors refuse to do that, patients have to change to another practice if they want to participate in the DMP. This might be a major barrier for the majority of elderly patients with chronic diseases such as diabetes for whom continuity of care plays an important role (9). Assuming that the rationales of the programmes (e.g. evidence-based, structured care, focussed on patient activation) are not questionable and favour better outcomes, it should be expected that family physicians who do not participate in the programme provide lower quality of care for their patients than those who are enrolled.

Unfortunately the statutory nationwide evaluation of the DMP for type-2 diabetes does not compare providers or patients which are enrolled with those which are not (10). Because of the short timeframe in which it was introduced, baseline measurements were not taken.

Fortunately in two areas of Germany in a larger study (ELSID- Diabetes study-evaluation of a large scale implementation of disease management programmes for patients with type 2 diabetes (11) a cross sectional approach with a cluster RCT intervention to optimize the implementation of the DMP is combined. This allows a more systematic comparison of patients and practices not enrolled or enrolled on the basis of clinical data, sick-fund claims data and patient experiences.

In the meanwhile more comprehensive frameworks such as the Chronic Care Model (CCM) receive widespread attention (12, 13) and it is currently evaluated which elements of this model may be most effective in improving care processes, costs and clinical outcomes (14, 15). The Patient Assessment of Chronic Illness Care (PACIC) instrument has been proven to be a reliable and valid tool (16) to measure quality of care according to the CCM and patient motivation according to the “5 A” principles with the PACIC-5A regarding different chronic diseases as diabetes (17, 18) or arthritis (19, 20). It addresses from a patient’s perspective and

experience to what extent provided care complies with the CCM. Since the aim of the DMPs is to structure care according to core elements similar to those of the CCM, we hypothesized that enrolled patients would achieve higher scores on the PACIC, suggesting better quality of care.

## **RESEARCH DESIGN AND METHODS**

For this study we draw a random sample of 3.546 patients (59.3% female) out of the total sample (n=20.625, 59.2% female) of the ELSID-study which is performed in two different German federal states, Rheinland-Pfalz and Sachsen-Anhalt. The study protocol for the ELSID-study and the inclusion criteria for patients were registered and published before (11). The protocol for the ELSID-study and for this survey were both fully approved by the ethics committee of the University of Heidelberg Medical Faculty.

In November 2006 all 3.546 patients received a mail with a cover letter directly from their health insurance (all patients where insured of the statutory regional health care funds, Allgemeine Ortskrankenkasse=AOK), including the questionnaire material labelled with a unique pseudonym for each patient and a postage-paid return envelope addressed to the study centre. Two weeks later all patients received a general reminding letter (without questionnaire) from the AOK again, regardless if they had sent their questionnaire back in the meanwhile or not. All patients could participate in the draw of a prize of 4 x € 250 (approx. USD 375) by sending in a separate postage-paid return envelope to the study centre. The questionnaire included sociodemographic data, some self reported health information (weight, height, smoking status, a list of chronic conditions in the patients words and the validated and culturally adapted German version of the PACIC-5A. This version contained 26 items, including 6 items to produce subscales for behavioural counselling according to the U.S. Preventive Taskforce recommendations (17). The questions request the patient to evaluate the

care they received from their family practitioner over the last 6 months with regard to several topics. The answers were given on a five-point Likert scale from 1 = almost never to 5 = almost always. After analysis the PACIC-5A supplies a five-scale profile of scores related to different aspects of providing care according to the CCM: patient activation, delivery system/practice design, goal setting/tailoring, problem solving/contextual, and follow-up/coordination. Additionally a sum-score can be generated. Another scoring option provides five items on each of the 5As subscales of assess, advise, agree, assist and arrange. All single items and the structure of the scores for the original source version in English language and the culturally adapted and validated German version are described elsewhere (18, 19).

All statistical analyses were conducted with SPSS, version 15.0. Comparisons between groups were performed with the Mann-Witney-Test for not normally distributed data and the chi square test respectively. The level of significance was  $p=.05$ .

## **RESULTS**

### **Respondent characteristics**

1.532 questionnaires were returned (response rate 42.2%), valid data could be obtained for 1.399 patients. Fig. 1 shows a flowchart for the conduct of the study and the response. For certain characteristics a non-responder analysis could be performed on the basis of claims data. On average responders were younger than non-responders (responder: 70.3 years [95% Confidence Interval (CI) 69.9; 70.7], non-responder 71.8 years [71.4; 72.2]),  $p<0.001$ . Of the responders 649 were male (46.4%) and 750 were female (53.6%) and of the non-responders 733 were male (35.4%) and 1337 (64.6%) were female.

Various characteristics of the study sample (separated in patients being enrolled in DMP (DMP) and patients not enrolled (Non-DMP) are shown in Table 1. Of the 1.399 included

patients 649 were male (46.4%) and 750 were female (53.6%). The mean age for the entire sample was 70.3 years (SD 8.5). There were no significant differences for other sociodemographic characteristics such as being married/living in partnership, lower education and low to medium annual household income. The average number of other (comorbid) self-reported medical conditions (including hypertension, coronary heart disease, chronic heart failure, ulcer, asthma, bronchitis, cancer, osteoarthritis and stroke) was 2.1 (minimum 0, maximum 8) within the total sample (Table 1). In average the patients were enrolled since 26.8 months (SD 9.0) into the DMP for type 2 diabetes.

#### PACIC scale

The average overall score on the PACIC items was 3.21 of a possible 5 for the patients enrolled in the DMP versus 2.86 for the non-DMP patients, under the care of family practitioners not enrolled into the DMP. This difference was statistically significant ( $p < 0.001$ ), see Table 2. Differences in the same direction were found on all five subscales of the PACIC on the same level of significance, except for patient activation where  $p$  was  $< 0.05$ . Nominally the difference was greatest at the follow-up coordination scale (mean difference = 0.44) and lowest at the patient activation scale (mean difference = 0.17).

#### 5As scoring

For the 5A scales again significant differences were found for all 5 subscales plus the sum-score ( $p < 0.001$ ) (Table 2). The mean for the overall 5A summary scale was 3.08 out of a possible 5 for the DMP patients versus a mean of 2.78 for the non-DMP patients. The highest mean differences were found for the 'assist' subscale (mean difference = 0.39) and the lowest for the 'agree' subscale (mean difference = 0.25).



## CONCLUSIONS

Patients with type-2 diabetes enrolled in a disease management program were more likely to receive patient-centred, structured and collaborative care according to the CCM. This large cross sectional study demonstrates significant differences in the quality of care as assessed by the PACIC-5A instrument between patients enrolled in the national DMP and patients which are not enrolled. These differences were largest for follow-up/coordination of care, goal setting/tailoring and for the problem solving/contextual scale. Similar findings were made for the 5As subscales where the largest differences in the same direction were found for ‘assist’, ‘advice’, and ‘assess’.

Compared to data for diabetic patients from an US study (18) German patients not participating in a DMP fall short in receiving aspects of care on the sum-score and all subscales of the PACIC and the 5As subscales. For example on the overall PACIC score the patients scored 2.7 versus 3.2 in the US study. In the US study patients scored in average 3.6 for ‘patient activation’ (our study: 3.1), 3.5 for ‘delivery system/practice design’ (our study: 3.3), 3.0 for ‘goal setting/tailoring’ (our study: 2.5), 2.9 for ‘follow up/coordination’ (our study: 2.7), 3.4 for ‘problem solving/contextual’ (our study: 3.0). This may be due to the higher age (our patients were in average 6.3 years older) and the higher number of co morbid conditions in our sample and to the fact that our patients in the non-DMP group received care in “routine” practices versus selected practices in the sample Glasgow et al draw for their validation study. Nevertheless patients enrolled into DMP receive better care as in the US study measured on the subscales for follow-up/coordination and similar care on all other subscales, including the 5As. In a different study with arthritis patients in Germany we found even lower scores for patients at similar age in the control arm (20). This finding might be interpreted as some external validation since care for patients with arthritis appears to be less structured because of the lack of clear recommendations for management in primary care than for diabetes and therefore lower scores on the PACIC-5A can be expected.

Our results have to be interpreted carefully. The return rate was modest, but a non-responder analysis could be performed, showing that non-responders were slightly older and showed a higher proportion of female patients. Our analysis is cross-sectional, with patients from one major type of regional health fund, with a market share of more than 40% and a higher proportion of elderly insureds with chronic conditions than other insurers. Differences between the two groups of patients under investigation exist, but do not allow any conclusion about a causal influence of the DMP. This may limit generalisability.

Strengths include the large and heterogeneous sample and the limitation of sampling bias within the patients of the health fund by means of clear selection criteria based on existing routine claims data and the draw of a random sample out of a very large representative sample of more than 20.000 patients with type-2 diabetes. Additionally, patients were not specifically informed that the aim of the study was to evaluate a DMP (which may have distorted results as DMPs are still under political or public debate from time to time), but to evaluate the actual care they receive by the doctor they consider as 'their' family practitioner.

In conclusion our results suggest that DMPs for diabetes as currently established in primary care in Germany may impact provided care significantly. The changes in daily practice which have been induced by the DMPs are recognized by patients as care that is more structured and that reflects the core elements of the CCM to a larger extent as usual care. In the perception of patients these differences exist and they may very well matter in terms of influencing clinical and economic outcomes (15). What makes this finding particularly interesting is that prior studies, evaluating the implementation of CCM elements, assessed provider structures or addressed process parameters. To our knowledge this is the first larger study assessing

different types of care (DMP vs. Non-DMP) and accordance of care with the CCM from a patients' perspective with the PACIC-5A instrument.

Our findings have to be completed later by the results of the final evaluation of the ELSID study. Of course it will be important to see if clinical parameters will improve in the DMP group. Nevertheless, these results might yield additional insight to the ongoing discussion on effective improvements of the quality of care for patients with chronic conditions.

#### Funding

This study is an investigator initiated trial, funded by the Federal Association of Statutory Regional Health Funds (AOK Bundesverband). The contract between the sponsor and the University of Heidelberg leaves the full responsibility for the scientific work, for the management of data and for analysis and publication to the investigators. The investigators are obliged to publish the results, no matter if positive or negative.

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**Table 1: Patient characteristics**

	<b>DMP (n=865)</b>	<b>Non-DMP (n=534)</b>	<b>p-value</b>
<b>Age (years)</b>	70.2 (8.3)	70.5 (8.9)	0.52
<b>Women</b>	465 (53.8)	285 (53.4)	0.89
<b>BMI</b>	30.3 (5.8)	30.3 (6.5)	0.86
<b>Smokers</b>	68 (8.0)	49 (9.3)	0.39
<b>Number of other chronic conditions</b>	2.1 (1.3)	2.1 (2.1)	0.51
<b>≤ 9 years of Education</b>	612 (70.8)	386 (72.3)	0.54
<b>Annual household income ≤ 21.000 €</b>	722 (83.5)	435 (81.5)	0.34
<b>Married / Living in partnership</b>	568 (65.7)	336 (62.9)	0.51

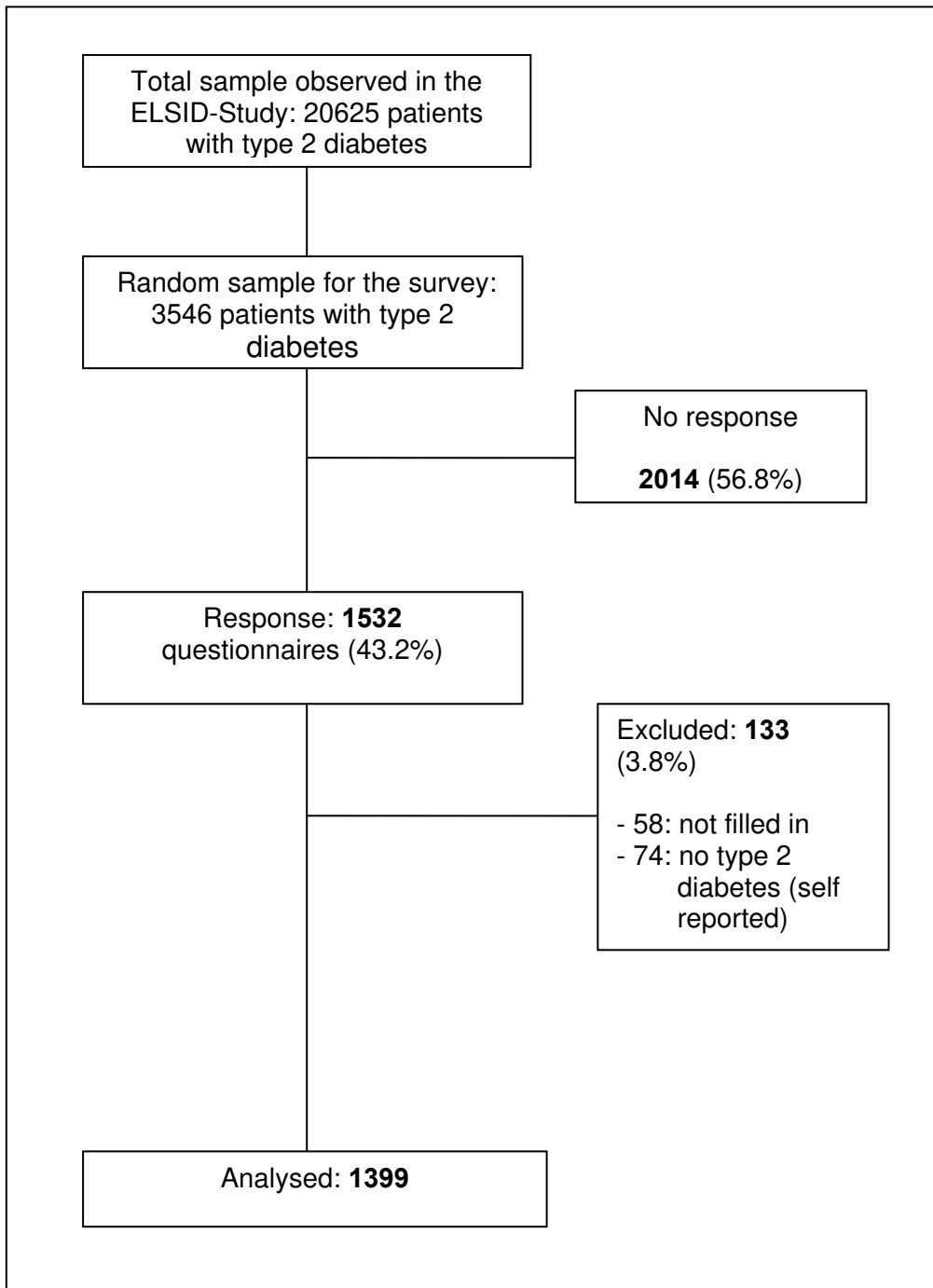
All Data were mean (SD) or number (percentage)

**Table 2: Results for overall PACIC scale, 5A scoring overall scale and all subscales, differences between DMP and Non-DMP patients**

Scale	DMP	95% CI	Non-DMP	95% CI	Significances of differences (p-values)
Overall PACIC score	3.26 (0.9)	3.14; 3.27	2.86 (0.9)	2.78;2.94	<0.001
Patient activation	3.26 (1.2)	3.18;3.34	3.09 (1.2)	2.98;3.19	<0,05
Delivery system / practice design	3.52 (0.9)	3.46;3.58	3.29 (0.9)	3.21;3.37	<0.001
Goal setting / tailoring	2.91 (1.1)	2.83; 2.98	2.50 (1.1)	2.40; 2.59	<0.001
Follow-up / coordination	3.13 (1.1)	3.06; 3.21	2.70 (1.1)	2.60;2.79	<0.001
Problem solving / contextual	3.39 (1.2)	3.31;3.47	3.04 (1.2)	2.93;3.14	<0.001
Overall 5A score	3.08 (1.0)	3.02;3.15	2.78 (1.0)	2.70; 2.86	<0.001
Assess	3.26 (1.1)	3.18;3.33	2.91 (1.1)	2.81;3.00	<0.001
Agree	3.24 (1.1)	3.17;3.32	2.99 (1.1)	2.89;3.09	<0.001
Advise	3.32 (0.9)	3.25;3.38	2.95 (1.0)	2.86;3.04	<0.001
Assist	3.21 (1.1)	3.13;3.28	2.82 (1.1)	2.72;2.91	<0.001
Arrange	2.87 (1.0)	2.80;2.93	2.55 (1.0)	2.46;2.64	<0.001

All data were mean (SD) or CI





**Figure 1** Flowchart response

